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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,296	06/02/2005	Manuela Guglielmo	5002-1074	8261
465 7590 05/26/2009 YOUNG & THOMPSON 209 Madison Street Suite 500 ALEXANDRIA, VA 22314			EXAMINER GULLEDGE, BRIAN M	
			ART UNIT 1619	PAPER NUMBER
			MAIL DATE 05/26/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/537,296

Applicant(s)

GUGLIELMO ET AL.

Examiner

Brian Guldge

Art Unit

1619

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 March 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/ICE)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Change of Examiner

This application has been reassigned from June Rogers to Brian Gulledge for the remainder of its prosecution. Applicant is advised that future communications should be directed to Brian Gulledge, who can be contacted at 571-270-5756, Monday–Thursday from 6:00 am until 3:00 pm.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 5, 2009 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. This is a “new matter” rejection. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the

application was filed, had possession of the claimed invention. Applicant previously presented claims 11 and 14 (newly added in the amendment filed May 30, 2008). These claims recite the inclusion of hydroxyproline and aspartic acid, but the claims do not require the two amino acids be complexed to a silanol. The deletion of the limitation that the two amino acids are complexed with a silanol is new matter. The composition discussed in the abstract (lines 1-3), specification (page 5, lines 20-24), and claims (claim 1) as originally filed always included complexation with a silanol. Applicant, in arguments received on January 5, 2009 and March 4, 2009, states that the disclosure contemplates the combination of hydroxyproline and aspartic acid to treat hair loss. However, the Applicant does not point out or cite any portion of the disclosure to support this limitation. Claims 12 and 13 were amended to depend from claim 11 in the claim amendments received on January 5, 2009, and are also rejected.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Desjonqueres (US Patent 6,001,378) in view of Hirama et al. (US Patent 4,713,397) and Zaveri (US Patent 6,376,557). Desjonqueres discloses compositions for treating alopecia, the compositions comprising organosilicone derivatives (abstract, lines 1-9). Suitable silanol derivatives disclosed by Desjonqueres include the complex of hydroxyproline and aspartic acid

with methylsilanol (column 4, lines 14-19). Amounts taught by Desjonqueres range from 0.1 to 1.0 wt% (column 6, examples 1-3), a range that overlaps the instantly recited range. And in cases involving overlapping ranges, the courts have consistently held that even a slight overlap in range establishes a *prima facie* case of obviousness. *In re Peterson*, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003). Desjonqueres also teaches the inclusion of preservatives, perfumes, and water in the composition (column 6, examples 1-3). Desjonqueres also discloses that the composition is applied topically (column 5, lines 45-54). Desjonqueres does not teach the further inclusion of octyl butyrate, glutamine peptides, benzyl nicotinate, and panthenol in the composition.

Hirama et al. discloses compositions for reducing hair fall-out comprising the skin vasodilator drug benzyl nicotinate (abstract, lines 1-8). The amount of benzyl nicotinate taught by Hirama et al. ranges from 0.1 to 2 wt% (column 1, lines 57-62), which overlaps the instantly recited range. The composition is applied topically (column 6, lines 2-5).

Zaveri discloses compositions for treating alopecia that are topically applied (abstract, lines 1-6). The active ingredients include from 0.5 to 4 wt% of Ancrine (a commercially available mixture of octyl butyrate and glutamine-containing peptides (column 4, lines 17-30). Zaveri also discloses the inclusion of the moisturizer panthenol in the composition (column 8, lines 8-9).

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have combined the ingredients taught by Desjonqueres, Hirama et al., and Zaveri into a single composition. Generally, it is *prima facie* obvious to combine compositions, each of which is taught by the prior art to be useful for same purpose (the above hair-loss treatment compositions applied topically), in order to form a third composition to be

used for the very same purpose. The idea for combining them flows logically from their having been individually taught in the prior art. See MPEP 2144.06.

The rejection of claims 8-14 was over Desjonqueres, Hiram et al., and Zaveri was presented in the action mailed September 4, 2008. In the response received on January 5, 2009, the Applicant argues that the amounts recited of the above ingredients would not have been obvious, and one of ordinary skill in the art would not expect the combination to achieve the recognized result. Applicant also further argues for the synergistic effect of the combination of ingredients, and both presents data in the arguments as well as states that these results are present in the specification.

The Examiner is not persuaded by these arguments. There is no evidence provided to support the statement that the amounts of the ingredients would not have been obvious as there is a synergistic effect from the combination of these elements in these amounts. The specification discloses data to support a "formulation" (which is not defined) that decreases hair loss (pages 7 and 8). The specification does not discuss a synergistic effect with regards to this/these formulations. The Applicant also provides data in the arguments to support this statement. However, a showing of unexpected results must be based on evidence, not argument. See MPEP 2145. And evidence of unexpected results must be supported by an appropriate affidavit or declaration (which has not been provided), and not by attorney statements. See MPEP 716.01(c)(I).

The argument that the skilled artisan would not expect the combination to have the recited properties is also not found persuasive. One of ordinary skill in the art would have

expected the combined composition to have the property of treating alopecia and reducing hair-loss, as each composition alone was taught to have this property.

In the response received on March 4, 2009, the Applicant argues that the composition interferes with the numerous mechanisms that cause hair loss “without exerting any local pharmacological or systemic action, which would be the case with an anti-hormone activity”, that the silanol complex promotes fibroblast proliferation and increases collagen crosslinks, and the combination of butyric acid and peptides rich in glutamine promotes hair growth.

The Examiner is not persuaded by these arguments. The assertion that the composition does not exert any local pharmacological or systemic action is not supported by any provided data or evidence. The Applicant also asserts properties of the silanol complex. Not only is no data or evidence provided, but Desjonqueres recognizes that the taught composition promotes cell metabolism and is a stimulant for the synthesis of collagen and elastin, which are related properties to that argued. Finally, the Applicant argues that the combination of butyric acid and peptides rich in glutamine promotes hair growth. There is both no evidence to support this statement, and the claims do not even recite the inclusion of butyric acid, so it is not clear how this fact, even if supported, relates to the compositions as recited.

Conclusion

No claims are allowed.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under

37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Gullledge whose telephone number is (571) 270-5756. The examiner can normally be reached on Monday-Thursday 6:00am - 3:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BMG

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612